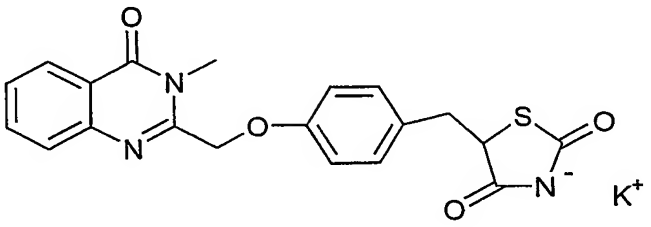
We claim:

1. A novel crystalline Form of 5-[4-[[3-methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione potassium salt, having the formula I



(I)

which is characterized by the following data :

DSC: Endotherms at 296.24, 307.64 °C,

small exotherm at 164.23 °C

exotherm at 291.90 °C

IR (KBr), (cm^{-1}): 507.4, 564.1, 612.7, 699.7, 778.9, 810.1, 1038.9, 1223.8, 1314.2, 1426, 1466, 1510.7, 1580.9, 1667.8, 3432.4,

X-ray powder diffraction (2θ): 6.20, 9.34, 12.16, 12.48, 15.06, 18.26, 18.80, 24.02,24.46, 26.70, 27.02, 27.48, 30.86

2. A process for the preparation of novel crystalline Form of 5-[4-[[3-methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione potassium salt, having the characteristics defined in claim 1, which comprises :

(i) synthesizing the 5-[4-[[3-methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione, employing known methods and dissolving in acetonitrile and xylene mixture,

(ii) heating the resulting solution at a temperature in the range of 60-90 °C to get clear solution,

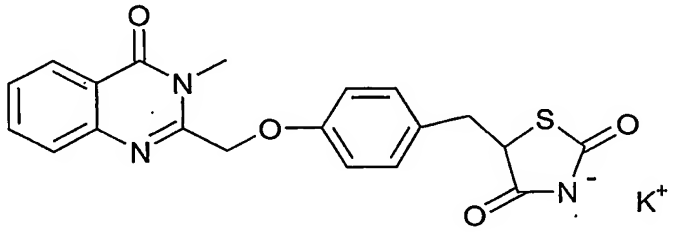
(iii) adding potassium tertiary butoxide dissolved in methanol at room temperature slowly with constant stirring to the solution obtained in step (ii),

(iv) stirring the reaction mixture at room temperature for a period in the range of 0.5-5 h to obtain precipitate,

(v) cooling the resulting solution and filtering the precipitate obtained in step (iv) above and

(vi) drying under vacuum at a temperature of 20-60 °C for a period in the range of 0.5 to 5 h to yield novel crystalline Form of 5-[4-[[3-methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione potassium salt.

3. A process for the preparation of polymorphic Form-I of 5-[4-[[3-methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione potassium salt of the formula I,



(I)

having the following characteristics

DSC: Endotherms at 301.17 °C, 311.82 °C,

Exotherm at 297.68 °C,

IR (KBr) (cm^{-1}): 503.9, 559.7, 609.7, 658.8, 609.7, 701.3, 772.9, 809.7, 1035.7, 1058.4, 1271.9, 1329.7, 1378.5, 1426, 1477.6, 1511.8, 1591.5, 1675.4, 1861.9, 3039.1, 3442.9,

X-ray powder diffraction (2θ): 6.44, 7.42, 9.28, 10.76, 11.24, 15.06, 16.16, 18.60, 25.06, 28.42, 30.40.

which comprises :

(i) synthesizing the 5-[4-[[3-methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione, employing known methods and dissolving in an organic solvent, at 60-80 °C

(ii) adding potassium tertiary butoxide dissolved in an organic solvent at temperature 40-60 °C

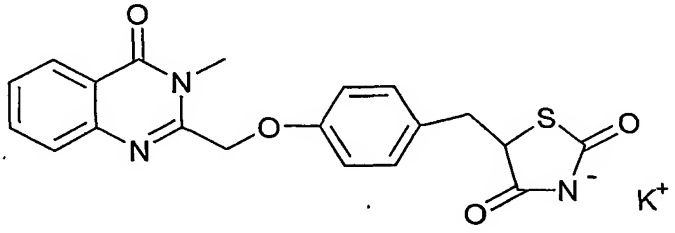
(iii) stirring the reaction mixture at a temperature of 20-90 °C for a period in the range of 1-10 h,

(iv) cooling the resulting solution and filtering the precipitate obtained in step (iii) above and

(v) drying under vacuum at a temperature of 40-70 °C for a period in the range of 1 to 6 h to yield Form-I of 5-[4-[[3-methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione potassium salt .

4. The process as claimed in claim 3, wherein the organic solvent is selected from methanol, methanol and xylene mixture, acetone and xylene mixture, ethanol, isopropanol, ethyl acetate, diethyl ketone and methyl isobutyl ketone.

5. A process for the preparation of polymorphic Form-I of 5-[4-[[3-methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione potassium salt of the formula I,



(I)

which comprises :

(i) synthesizing the 5-[4-[[3-methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione, employing known methods and dissolving in an organic solvent, at room temperature,

(ii) adding potassium tertiary butoxide dissolved in an organic solvent at room temperature,

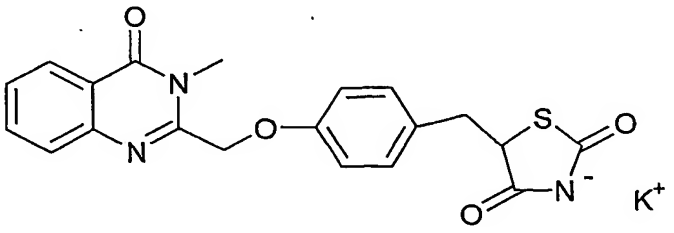
(iii) stirring the reaction mixture at room temperature for a period in the range of 2-20 h,

(iv) cooling the resulting solution and filtering the precipitate obtained in step (iii) above and

(v) drying under vacuum at a temperature of 40-70 °C for a period in the range of 1 to 6 h. to yield Form-I of 5-[4-[[3-methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione potassium salt .

6. The process as claimed in claim 3, wherein the organic solvent is selected from DMF, 1,4-Dioxane or 1,4- Dioxane and xylene mixture.

7. A process for the preparation of polymorphic Form-I of 5-[4-[[3-methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione potassium salt of the formula I,



(I)

which comprises :

(i) synthesizing the 5-[4-[[3-methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione potassium salt from any of the above procedure,

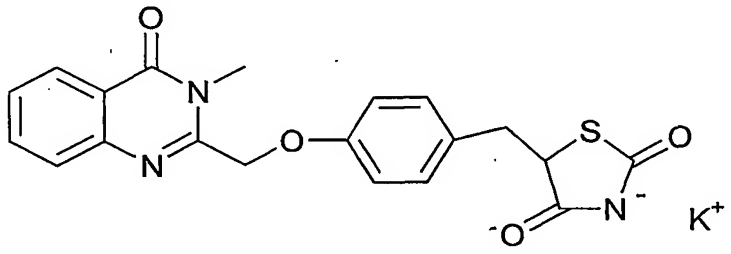
(ii) dissolving in DMSO at 50-80 ^{0}C to get clear solution

(iii) storing the reaction mixture at room temperature for 1-8 weeks

(iv) filtering the precipitate obtained in step (iii) above and

(v) drying under vacuum at a temperature of 40-70 °C for a period in the range of 1 to 6 h to yield Form-I of 5-[4-[[3-methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione potassium salt .

8. A pharmaceutical composition, which comprises a novel crystalline Form of 5-[4-[[3-methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione potassium salt, having the formula I



(I)

as defined in claim 1 and a pharmaceutically acceptable carrier, diluent, excipient or solvate.

9. A pharmaceutical composition as claimed in claim 8 in the form of a tablet, capsule, powder, syrup, solution or suspension.

10. A pharmaceutical composition as claimed in claims 8 and 9 for the treatment and / or prevention of type II diabetes, glucose intolerance, leptin resistance, dyslipidaemia, disorders related to Syndrome X including hypertension, obesity, insulin resistance, atherosclerosis, hyperlipidemia, coronary artery disease, polycystic ovarian syndrome (PCOS) and other cardiovascular disorders; renal diseases including glomerulonephritis, glomerulosclerosis, nephrotic syndrome, hypertensive nephrosclerosis, nephropathy, disorders to related endothelial cell activation, psoriasis, osteoporosis, dementia, diabetic complications, inflammatory bowel diseases, myotonic dystrophy, pancreatitis, arteriosclerosis, retinopathy or xanthoma.

11. A method of preventing or treating hyperlipemia, hypercholesteremia, hyperglycemia, osteoporosis, obesity, impaired glucose tolerance, atherosclerosis, leptin resistance, insulin resistance or diseases in which insulin resistance is the underlying pathophysiological mechanism comprising administering a novel crystalline Form of 5-[4-[[3-methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione potassium salt as claimed in claim 1 or a pharmaceutical composition according to claim 8 or 9 to a patient in need thereof.

12. A method of reducing total cholesterol, body weight, blood plasma glucose, triglycerides, LDL, VLDL or free fatty acids or increasing HDL in the plasma comprising administering a novel crystalline Form of 5-[4-[[3-methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione potassium salt, as defined in claim 1 or a pharmaceutical composition according to claim 8 or 9 to a patient in need thereof.

13. A method of preventing or treating hyperlipemia, hypercholesteremia, hyperglycemia, osteoporosis, obesity, impaired glucose tolerance, atherosclerosis, leptin resistance, insulin resistance or diseases in which insulin resistance is the underlying pathophysiological mechanism comprising administering a novel crystalline Form of 5-[4-[[3-methyl-4-oxo-3,4-dihydroquinazolin-2-yl]methoxy]benzyl]thiazolidine-2,4-dione potassium salt as claimed in claim 1 or a pharmaceutical composition according to claim 8 or 9 in combination / concomittant with HMG CoA reductase inhibitor; cholesterol absorption inhibitor; antiobesity drug; lipoprotein disorder treatment drug: fibrate; hypoglycemic agent: insulin; biguanide; sulfonylurea; thiazolidinedione; dual PPARα and γ agonist or a mixture thereof or their combination within such a period so as to act synergistically and/ or additively to a patient in need thereof.

14. A method according to claim 11 and 13 wherein the disease is type II diabetes, impaired glucose tolerance, dyslipidemia, disorders related to Syndrome X including hypertension, obesity, insulin resistance, atherosclerosis, hyperlipidemia, coronary artery disease, polycystic ovarian syndrome (PCOS) and other cardiovascular disorders; renal diseases including glomerulonephritis, glomerulosclerosis, nephrotic syndrome, hypertensive nephrosclerosis, nephropathy, disorders to related endothelial cell activation, psoriasis, osteoporosis, dementia, diabetic complications, inflammatory bowel diseases, myotonic dystrophy, pancreatitis, arteriosclerosis, retinopathy or xanthoma.

15. A method of reducing total cholesterol, body weight, blood plasma glucose, triglycerides, LDL, VLDL or free fatty acids or increasing HDL in the plasma comprising administering a compound of formula (I), as defined in claim 1 or a pharmaceutical composition according to claim 8 or 9 in combination / concomittant HMG CoA reductase inhibitor; cholesterol absorption inhibitor; antiobesity drug; lipoprotein disorder treatment drug: fibrate; hypoglycemic agent: insulin; biguanide; sulfonylurea; thiazolidinedione; dual PPARα and γ agonist or a mixture thereof which may be administered together or within such a period as to act synergistically together to a patient in need thereof.